Remarks

Claim 28

Examiner has indicated that the Applicant has cancelled claim 28, but has also submitted amendments therefor. After the Examiner's review of amended claim 28, it appears to differ from claim 26 only in the functional language of the preamble. The examiner has deduced that it was, in fact, Applicant's intent to cancel claim 28, and thus, it has not been examined, and remains cancelled.

Applicants have cancelled Claim 28.

Specification

The specification is objected to because of the list of references cited therein. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, 'the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, or on Applicant's PTO-1449, they have not been considered. Further, since any references that are cited on either form PTO-892, or on Applicant's PTO-1449 will be printed on the face of any patent issuing herefrom, the listing in the specification is unnecessary and will be redundant. The list must be deleted from the specification.

Applicants traverse. Applicants understanding of MPEP § 609A is that applicants can not use listed references in application as a surrogate for citing references, and that for references to be considered they must be either cited on the Examiner PTO-892 or on Applicants PTO-1449 form. As such, Applicants' respectfully request the present objection be removed.

Claim Rejections -35 USC § 112

The Examiner has indicated that Claims 1 and 30 set forth that the drug is "intimately mixed" into the polymer. However, claims 7-10, 32, and 35 appear to claim that the two are combined somewhat differently (e.g. claim 7 claims that the agent is "coated onto the tissue-contacting surface"). Applicant was thereby requested to review these claims closely to determine if they indeed conflict with the claims from which they depend.

Applicants have cancelled claims 7-10, 32, and 35.

Rejection of Claims 1-9, 11-12, 26, 30-32, and 35 under 35 USC § 103

Claims 1-9, 11, 12, 26, 30-32, and 35 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629). Helmus was cited for teaching substantially all the claimed subject matter including an implantable medical device (figure 1, col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46). The Examiner specifically points out that col. 71 lines 57 -62 specify the OUTER layer, not the reservoir layer. In col. 7, lines 57 -62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in both the reservoir and outer layer. The Examiner indicates that Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such dexamethasone. Fearnot is also cited for teaching the of as use dexamethasone in a drug embedded outer layer of a catheter. The Examiner, thereby concluded, it would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

Applicants respectively traverse.

Fearnot teaches the application teaches that the top-coat of at least one porous top layer is essential for use with coatings of implantable medical devices:

- Column 3, lines 6-12 – "Applicants have discovered that the degradation of an agent, a drug or a bioactive material applied to such a device can be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer . . ."
- Column 3, lines 50-57 – "The at least one porous layer is preferably composed of a polyimide, parylene, or parylene derivative . . .";
- Column 4, lines 13-16 – "The at least one porous layer can alternatively be applied . . ."

Fearnot teaches that the top porous layer is preferably made of polyimide, parylene, or a parylene derivative.

Helmus respectively teaches the presence of having a top-coat, but Helmus requires the bottom and the top coat contain reservoirs – these reservoirs are formed from porogens initially placed in the coating. As such, Helmus does not appear to teach the tissue-contacting polymer surface of the catheter is intimately mixed with the drug.

Helmus has two layers. A outer polymeric surface-layer overlying a inner polymer layer that incorporates the agent (23) (see figures 1b and 1c, or 2b and 2c). The outer-layer has an elutable component (22) which is eroded to form pores to the inner polymer area containing agent (23). No where is there formed an outer polymer layer intimately mixed with the drug. By having an outer polymer layer coating the active drug layer one skilled in the art would recognize that Helmus actually teaches away from directly mixing the drug with the surface polymer.

Because neither Fearnot nor Helmus teach an overcoating of a non-porous polymer intimately mixed with a steroidal anti-inflammatory agent, applicants respectfully request the present rejection be removed.

Rejection of Claims 1-9, 11-12, 26, 30-32, and 35 under 35 USC § 103

With regard to the method claims, claim 26, which claims a method of use, the examiner points out that the claim only contains one broad method step of "implanting," the rest is merely structure. The Examiner further points out that claims 30-32, and 35 merely claim the basic assembly steps necessary to put anything together (e.g. "coupling"). Again, the rest is merely structure.

Applicants traverse.

Applicants realize their method is claim is broadly drafted with regard to the method step. It is intended to broadly claim the method of implanting applicants' device.

Rejection of Claims 1-9, 11-12, 26, 30-32, and 35 under 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus in view of Fearnot as applied to claim 1 above, and further in view of Hendriks et al '151. Helmus as modified by Fearnot teaches all the claimed subject matter of claim 23 except for the anti-inflammatory agent being covalently bonded to the polymer surface. Hendriks teaches a catheter (col. 4, line 8), having an anti-inflammatory agent (col. 4, lines 23-24), wherein the agent is covalently bonded to the surface of the catheter (col.

4, line line 33-35).It would have been obvious to one of ordinary skill in the art to use the covalent bonding as taught by Hendriks to embed the anti-inflammatory agent of Chait as modified by Fearnot into layer 18 of Fearnot.

Rejections to claim 10 have been rendered moot by cancellation of this claim.

Conclusion

In view of the cancelled claims and arguments submitted with the present response, Applicants' believe the claimed subject matter is novel and unobvious over the prior art and anxiously await the examiner's review and approval to issue the remaining claims.

Respectfully submitted,

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